K021581
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JUL 12 2002

510(k) Summary

Z-MEDICA, LLC
35 BUDNEY ROAD
NEWINGTON, CT 06111
860.667.8888

CONTACT PERSON

BART GULLONG
VICE-PRESIDENT

REVISED:
JUNE 28, 2002

510(k) Summary

Trade Name	Hemosorb
Device Class	Unclassified
Classification Panel	General and Plastic Surgery
Common Name	Traumatic Wound Dressing
Predicate Device	Sorbastace K-965034 Company: Hemostace
Contact Person	Bart Gullong, Vice-President
Company Name	Z-Medica, LLC
Company Address	35 Budney Road Newington, CT 06111
Company Phone #	860.667.2201
Revised	June 28, 2002

Statement of Indications for Use

Hemosorb is intended as a topical dressing for the local management of bleeding wounds such as minor cuts, lacerations, and abrasions.

Device Description

Hemosorb is a bulk granular hemostatic agent, which is placed on or into a wound to effect adsorption, and coagulation of same.

The effect of Hemosorb is purely physical, not chemical in nature. Hemosorb has an unusually high adsorptive effect on liquid. This rapid adsorption of water as a blood component serves to concentrate platelets, and increase the speed and effect of their clotting capabilities. This rapid adsorption also diminishes the volume of the liquid present in the wound as a sponge effect, to facilitate clotting.

The product is designed and packaged to be easily packed, carried and applied using only one hand. It is well suited for wounds, to create hemostasis by coagulation.

Hemosorb has been tested in-house at On Site, at Hartford Hospital, by Johnson & Johnson, and at the University of Connecticut by Micro Test Laboratories, and at USUHS for the military. Testing and results are enclosed.

In Invitro and Invivo testing on rats, rabbits and larger mammals at the University of Connecticut, Hemosorb consistently performed well above a cologen-based hemostatic agent in rate of coagulation and reduction of bleeding time.

Tests of Hemosorb by the UConn Chemistry Department showed a lower toxicity score of rat histopathology following application of compound to stop bleeding than other hemostatic agents. Toxicity was only 10% higher than the inert control device used.

Tests by the Chief of Surgery at VAMC, Newington, CT, conducted at Hartford Hospital on rats and pigs' livers and skin, found Hemosorb was superior to other hemostatic agents in its ability to stop bleeding.

During March 2002, testing on large mammals (animals) was completed. USUHS and the Office of Naval Research developed a large animal model of lethal uncontrolled hemorrhage. This was used to test whether the use of various hemostatic agents (in addition to standard dressing) would decrease bleeding and improve early survival. The study was highly controlled. The following is a brief summary of Hemosorb's successful results:

Mortality Rate:	No Dressing = 80% Standard Dressing = 33.4% Standard Dressing with Hemosorb = 0%
Blood Loss	Hemosorb = lowest volume of blood loss of tested hemostatic agents.

Biocompatibility testing was completed by ISO 17025 Certified MicroTest Laboratories, Inc., of Agawam, Mass. The tests included:

Test	Sample #	Dated
Agar Overlay Cytotoxicity Test	02-00480	01/29/02
Water Adsorption Rate	02-00254	01/21/02
Skin Sensitization	01-06556	12/21/01
Skin Irritation	01-06555	12/07/01
Intracutaneous Test	01-06554	11/30/01
MEM Elution Cytotoxicity Test	01-06492	11/08/01
Muscle Implant	01-06476	01/08/01

In summary, Hemosorb performed extremely well.

Hemosorb is a safe, effective, low cost wound dressing which is substantially alike in purpose, characteristic, process, and result to Sorbastace, and thereby eligible for approval under 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Mr. Francis X. Hursey
President
On Site Gas Systems, Inc.
35 Budney Road
Newington, Connecticut 06111

Re: K021581
Trade/Device Name: Hemosorb
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 9, 2002
Received: May 14, 2002

Dear Mr. Hursey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021581

STATEMENT OF INDICATIONS FOR USE

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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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